REMARKS/ARGUMENTS

This response is timely filed with 3 months of mailing of the Office Action from the US Patent Office.

Claims 19-31 are currently pending.

No amendments to claims 19-31 are made at this time.

Rejection of Claims 19-31 under 35 U.S.C. § 103(a)

Claims 19-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama (US Patent No. 6,485,760, hereinafter "Matsuyama") in view of Hoffman (The Complete Illustrated Herbal, *Practical Herbalism, The Preparation of Herbs*, 1996, pages 20-33, hereinafter "Hoffman"), McPeak (US Patent No. 6,303,586, hereinafter "McPeak"), LaGrone (US Patent No. 6,407,068, hereinafter "LaGrone"), Matsutani et al. (US Patent No. 6,407,068, hereinafter "Matsutani"), Shanmyasudndam et al. (US Patent No. 5,980,902, hereinafter "Shanmyasundam"). Applicants respectfully traverse this rejection for at least the following reasons.

Claims 19-31 pertain to soft gel capsules that are prepared by a unique process. The process by which the soft gel capsule is prepared includes the steps of heating rice bran oil to about 35° C in a container, adding a filler, adding corosolic acid, continuously stirring the mixture, and encapsulating the mixture in the soft gel capsule. The result is a soft gel capsule that ***encapsulates a liquid*** containing corosolic acid.

Matsuyama, the primary reference, discloses an oral composition, a hard "tablet" (See column 5, line 50 through column 6, line 20) with a "***powered herbal extract*** containing corosolic acid". (Emphasis added.) As the Office Actions of September 9, 2003, April 7, 2004 and November 16, 2004 note, Matsuyama fails to teach or suggest in any of its disclosure that anything but a tablet that contains a "***powdered herbal extract containing Corosolic acid***" (Emphasis added).

As noted above, the present invention is drawn to a ***soft gel*** capsule that ***encapsulates*** a ***liquid*** that contains corosolic acid. Matsuyama is devoid of any teaching for such an encapsulated liquid composition.

Furthermore, Matsuyama fails to provide any motivation or an expectation of success such that one having ordinary skill in the art to formulate a ***soft gel capsule that encapsulates a liquid that contains corosolic acid***.

Additionally, Matsuyama fails to teach or suggest or provide any motivation or an expectation of success to one having ordinary skill in the art to formulate a ***soft gel capsule that encapsulates a liquid that contains corosolic acid*** by a process that includes heating rice bran oil, adding filler, adding corosolic acid and then ***encapsulating*** the mixture in the ***soft gel capsule***.

Hoffman, a secondary reference, fails to remedy the deficiencies of Matsuyama. Hoffman, is a general teaching that ***dried herbs*** can be placed into a two-piece gelatin capsule. As Hoffman shows at page 26, these are gelatin capsules that come in two pieces. The ***powdered herbs*** must be placed into the two halves. One half of the capsule has a larger circumference than the second one half of the capsule. The two halves are pushed together with the larger half sliding over the smaller half, to form a seal and the two-piece capsule. As a consequence, ***the herbs are present in the capsule as a powdered dry composition***.

Hoffman fails to teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art to place a powdered dried herb into a liquid. Additionally, with the technology utilized by Hoffman, a liquid would not be contained in a two-piece gelatin capsule. This is best demonstrated by the depiction at page 26 of Hoffman, showing taking a powdered herb and bringing the two halves of a two-piece gelatin capsule together. This would be impossible with a liquid, as the liquid would spill out of the halves of the capsule. The present invention utilizes soft gel capsule technology, wherein a ***liquid*** (rice bran oil) that contains the corosolic acid is ***encapsulated*** by a hermetically sealed ***soft gel capsule***. A soft gel capsule is simply not equivalent to a two-piece gelatin capsule.

Hoffman is completely devoid of any teaching or suggestion and fails to provide any motivation or an expectation of success such that one having ordinary skill in the art would formulate a ***soft gel capsule that encapsulates a liquid that contains corosolic acid***.

Additionally, Hoffman fails to teach or suggest or provide any motivation or an expectation of success to one having ordinary skill in the art to formulate a ***soft gel capsule that encapsulates a liquid that contains corosolic acid*** by a process that includes heating rice bran oil, adding filler, adding corosolic acid and then ***encapsulating*** the mixture in the ***soft gel capsule***.

In stark contrast, the present invention provides a ***soft gel capsule*** that ***encapsulates*** a ***flowable liquid*** that contains corosolic acid ***liquefied*** in rice bran oil.

Consequently, neither Matsuyama or Hoffman, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a ***soft gel capsule*** that ***encapsulates liquified corosolic acid*** could be prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid, and ***encapsulating*** the mixture into a ***soft gel capsule***.

It is well settled that it is not proper to selectively extract individual elements from a reference and then combine those selectively extracted elements to arrive at a claimed combination. Rather in considering the elements within the reference, the reference must be considered as a whole, it being impermissible to pick and choose from a reference only so much of it as will support a given position. *In re Wesslau*, 353, F.2d 238, 147 USPQ 391 (CCPA 1965); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). There is a rigorous requirement that there must be some motivation, suggestion or teaching of the desirability for selecting the elements and combining those elements in the specific combination of the invention, and the motivation, suggestion or teaching must be disclosed in the prior art. *In re Kotzab*, 217 F.3d 1365, 54 USPQ2d 1308, 1316 (Fed. Cir. 2000); *In re Oetiker*, 977 F.2d 14343, 24 USPQ2d 1443 (Fed. Cir. 1992). In the absence of such motivation, suggestion or teaching, it is immaterial that some, or even all, of the elements in a specific combination of an invention are known in the prior art.

This is the case at hand. Neither Matsuyama or Hoffman, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a ***soft gel capsule*** that ***encapsulates liquified corosolic acid*** could be prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid, and ***encapsulating*** the mixture into a ***soft gel capsule***.

As clearly stated in *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453 (Fed. Cir. 1998):

> As this court has stated, "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co., 713F2d 693, 698,218 U.S.P.Q. (BNA) 865, 870 (Fed. Cir. 1983)*; see also *Richdel, Inc. v. Sunspool Corp., 714 F2d 1573, 1579-80, 219 U.S.P.Q. (BNA) 8, 12 (Fed. Cir. 1983)* ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." *Sensonics, Inc.. v. Aerosonic Corp., 81 F.3d 1566, 1570, 38 U.S.P.Q.2D (BNA) 1551,1554 (Fed. Cir. 1996).*

and:

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the citations within the reference to create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited reference(s) for combination in the manner claimed.

Neither Matsuyama or Hoffman, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a ***soft gel capsule*** that ***encapsulates liquified corosolic acid*** could be prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid, and ***encapsulating*** the mixture into a ***soft gel capsule***.

Neither Matsuyama nor Hoffman provide the motivation, suggestion or teaching, and no showing has been made otherwise identifying in these references such a motivation, suggestion or teaching, for selecting elements from the cited reference to render obvious the method recited in Claims 19 through 31, and the invention cannot be used as a blueprint for identifying a suggestion or motivation.

As stated in *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d (BNA) 1614 (Fed. Cir. 1999):

> Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1352, 48 U.S.P.Q.2D (BNA) 1225, 1232 (Fed. Cir. 1998)* (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet, 149 F.3d 1350, 1359, 47 U.S.P.Q.2D (BNA) 1453, 1459 (Fed. Cir. 1998)* ("the Board must identify specifically... the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch, 972 F2d 1260, 1265, 23 USP.Q.2D (BNA) 1780, 1783 (Fed. Cir. 1992)* (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine, 837F.2d 1071, 1075, 5 U.S.P.Q.2D (BNA) 1596, 1600 (Fed. Cir. 1988)* (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297, 227 U.S.P.Q. (BNA) 657, 667 (Fed. Cir 1985)* (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham, 383 U.S. at 18, 148 U.S.P.Q. (BNA) at 467* ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil, 774 F2d 1132, 1138, 227 U.S.P.Q. (BNA) 543, 547 (Fed. Cir. 1985)* ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case the Board fell into the hindsight trap.

McPeak, a tertiary reference, discloses stabilized rice bran derivatives that are provided to an individual in a variety of forms, such as by simply sprinkling the derivative on another food substance (i.e., salad, bread, cereal, etc.) being a major ingredient in a multigrain ready to eat cereal, incorporating it into a baked product (breads, muffins, waffles, etc), pasta, healthy dessert and snacks (athletic bar, healthy drink, etc.) and high fiber foods (See Column 6, lines 19 through 24).

McPeak fails to remedy the deficiencies of Matsuyama or Hoffman, alone or in combination.

McPeak fails to teach or suggest, provide any motivation or an expectation of success that any type of rice bran derivative could be used to ***solvate any herb, least of all corosolic acid***. McPeak is devoid of any teaching or suggestion that a rice bran derivative could be heated, a filler added with any herb, such as corosolic acid, and then the resulting ***liquid*** composition ***encapsulated*** into a ***soft gel capsule***.

McPeak fails to teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art the preparation of a ***soft gel capsule with any rice bran derivative.*** Moreover, McPeak fails to teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art the preparation of a soft gel capsule a herb, let alone with corosolic acid. Additionally, McPeak fails to teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a ***soft gel capsule*** containing corosolic acid could be prepared by heating rice bran oil, adding a filler, adding a herb, i.e., corosolic acid, and ***encapsulating*** the liquid mixture into a ***soft gel capsule***.

Consequently, none of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a ***soft gel capsule*** that ***encapsulates liquified corosolic acid*** could be prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid, and ***encapsulating*** the mixture into a ***soft gel capsule***.

LaGrone, a quaternary reference, fails to remedy the deficiencies of Matsuyama, Hoffman and McPeak, alone or in combination.

LaGrone teaches the use of silica to prevent diabetes.

LaGrone does not teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art to use silica in a ***soft gel capsule***.

LaGrone does not teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art to use silica ***in combination with corosolic acid in a soft gel capsule***.

LaGrone does not teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art to use silica ***in combination with rice bran oil in a soft gel capsule, let alone in a soft gel capsule***.

Consequently, none of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a ***soft gel capsule*** that ***encapsulates liquified corosolic acid*** could be prepared by heating rice bran oil, adding a filler such as silica, adding the herb, i.e., corosolic acid, and ***encapsulating*** the mixture into a ***soft gel capsule***.

Shanmyasundam fails to remedy the deficiencies of Matsuyama, Hoffman, McPeak and LaGrone, alone or in combination.

Shanmyasundam discloses an extract of *Gymnema sylvestre*.

Shanmyasundam does not teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art to use *Gymnema sylvestre* in a ***soft gel capsule***.

Shanmyasundam does not teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art to use an extract of *Gymnema sylvestre* ***in combination with corosolic acid in a soft gel capsule***.

Shanmyasundam does not teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art to use an extract of *Gymnema sylvestre* ***in combination with rice bran oil in a soft gel capsule, let alone in a soft gel capsule***.

Consequently, none of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a ***soft gel capsule*** that ***encapsulates liquified corosolic acid*** could be prepared by heating rice bran oil, adding a filler, adding herbs, i.e., corosolic acid and an extract of *Gymnema sylvestre*, and ***encapsulating*** the mixture into a ***soft gel capsule***.

Matsutani fails to remedy the deficiencies of Matsuyama, Hoffman, McPeak, LaGrone and Shanmyasundam, alone or in combination.

Matsutani discloses ***coating*** a ***tablet*** with bee's wax.

In contrast, the presently claimed subject matter incorporates the bee's wax ***within*** a ***soft gel capsule***.

Matsutani does not teach or suggest nor provide any motivation or an expectation of success for the use of bee's wax ***within*** a soft gel capsule.

Matsutani does not teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art to use bee's wax ***in combination with corosolic acid in a soft gel capsule***, let alone ***within*** a soft gel capsule.

Matsutani does not teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art to use bee's wax ***in combination with rice bran oil in a soft gel capsule, let alone in a soft gel capsule***, especially where the bee's wax is ***within*** the soft gel capsule.

Consequently, none of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a ***soft gel capsule*** that ***encapsulates liquified corosolic acid*** could be prepared by heating rice bran oil, adding a filler such as ***bee's wax***, adding the herb, i.e., corosolic acid, and ***encapsulating*** the mixture into a ***soft gel capsule***, such that the bee's wax is ***within*** the soft gel capsule.

It is well settled that it is not proper to selectively extract individual elements from a reference and then combine those selectively extracted elements to arrive at a claimed combination. Rather in considering the elements within the reference, the reference must be

considered as a whole, it being impermissible to pick and choose from a reference only so much of it as will support a given position. *In re Wesslau*, 353, F.2d 238, 147 USPQ 391 (CCPA 1965); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). There is a rigorous requirement that there must be some motivation, suggestion or teaching of the desirability for selecting the elements and combining those elements in the specific combination of the invention, and the motivation, suggestion or teaching must be disclosed in the prior art. *In re Kotzab*, 217 F.3d 1365, 54 USPQ2d 1308, 1316 (Fed. Cir. 2000); *In re Oetiker*, 977 F.2d 14343, 24 USPQ2d 1443 (Fed. Cir. 1992). In the absence of such motivation, suggestion or teaching, it is immaterial that some, or even all, of the elements in a specific combination of an invention are known in the prior art.

This is the case at hand. None of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a ***soft gel capsule*** that ***encapsulates liquified corosolic acid*** could be prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid, and ***encapsulating*** the mixture into a ***soft gel capsule***.

As clearly stated in *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453 (Fed. Cir. 1998):

> As this court has stated, "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co., 713F2d 693, 698,218 U.S.P.Q. (BNA) 865, 870 (Fed. Cir. 1983)*; see also *Richdel, Inc. v. Sunspool Corp., 714 F2d 1573, 1579-80, 219 U.S.P.Q. (BNA) 8, 12 (Fed. Cir. 1983)* ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." *Sensonics, Inc.. v. Aerosonic Corp., 81 F.3d 1566, 1570, 38 U.S.P.Q.2D (BNA) 1551,1554 (Fed. Cir. 1996).*

and:

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the citations within the reference to create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited reference(s) for combination in the manner claimed.

As stated in *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d (BNA) 1614 (Fed. Cir. 1999):

> Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1352, 48 U.S.P.Q.2D (BNA) 1225, 1232 (Fed. Cir. 1998)* (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet, 149 F.3d 1350, 1359, 47 U.S.P.Q.2D (BNA) 1453, 1459 (Fed. Cir. 1998)* ("the Board must identify specifically... the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch, 972 F2d 1260, 1265, 23 USP.Q.2D (BNA) 1780, 1783 (Fed. Cir. 1992)* (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine, 837F.2d 1071, 1075, 5 U.S.P.Q.2D (BNA) 1596, 1600 (Fed. Cir. 1988)* (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297, 227 U.S.P.Q. (BNA) 657, 667 (Fed. Cir 1985)* (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham, 383 U.S. at 18, 148 U.S.P.Q. (BNA) at 467* ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil, 774 F2d 1132, 1138, 227 U.S.P.Q. (BNA) 543, 547 (Fed. Cir. 1985)* ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case the Board fell into the hindsight trap.

None of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a ***soft gel capsule*** that ***encapsulates liquified corosolic acid*** could be prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid, and ***encapsulating*** the mixture into a ***soft gel capsule***.

It is believed that all of the issues raised in the Office Action have been addressed herein. Should the Examiner maintain the rejection of any of the pending claims, it is respectfully requested that it be pointed out with particularity how the cited reference meets each and every term of each claim with respect to which rejection is maintained, and if the rejection is based on obviousness, identification of the specific motivation, suggestion or teaching in the reference for combining elements in the specific combination off the invention.

Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

This application now stands in allowable form and reconsideration and allowance is respectfully requested. If a telephonic consultation would help to expedite the processing of the application, the Examiner is urged to contact the attorney below at the Examiner's convenience.

Respectfully submitted,

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Date: February 16, 2005

By: 

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